K102013

OCT 2 9 2010

Section 5. 510(k) Summary

Prepared: July 15, 2010

Submitter:

Company Name:	Canon Inc.
Company Address:	30-2 Simomaruko 3-chome, Ohta-ku Tokyo 146-8501, Japan
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Proposed Device:

Reason For 510(k):	New Model
Trade Name:	Canon
Model Name:	DIGITAL RETINAL CAMERA CR-2
Classification Name:	86HKI, Ophthalmic camera
FDA 510(k) #:	To be assigned

Predicate Device:

Trade Name:	Canon
Model Name:	DIGITAL RETINAL CAMERA CR-1 MarkII
Classification Name:	86HKI, Ophthalmic camera
FDA 510(k) #:	K090466

Description of Device:

The DIGITAL RETINAL CAMERA CR-2 is used for taking digital images of retina of human eye without a mydriatic.

Canon EOS Digital Camera is mounted to the CR-2. Images can be viewed immediately, making procedures more efficient with many different applications, such as telemedicine and electronic filing.

Intended Use:

The device is intended to be used for taking digital images of the retina of the human eye without a mydriatic.

Comparison to Predicate:

The CR-2's imaging principle and intended use are the same as those of CR-1 Mark II.

The CR-2 is reduced dimensions and weight as compared with the CR-1 Mark II. The optical components, alignment and most of the specifications are the same or better than CR-1 Mark II.

Performance testing:

The following testing was performed on the DIGITAL RETINAL CAMERA CR-2 to demonstrate that it meets all requirements and is equivalent to the predicate device:

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Electrical Safety & Electromagnetic Compatibility

CR-2 was tested in accordance with IEC60601-1 and IEC60601-1-2, and was found to meet all requirements of these standards.

Requirements for Ophthalmic instruments

CR-2 was tested in accordance with ISO15004-1:2006 and ISO15004-2:2007, and was found to meet all requirements of these standards.

Conclusion:

The Performance Data demonstrate that CR-2 is as safe and effective as the predicate devices. Based on the information in this submission, similarity to the predicate device (CR-1 Mark II), and the results of our design control activities, it is our opinion that the DIGITAL RETINAL CAMERA CR-2 described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc.
c/o Mr. Koji Kubo, Manager
Cosmos Corporation, Tokyo Office
3F, 2-17-6 Akebono-cho
Tachikawa-shi, Tokyo
190-0012 Japan

OCT 29 2010

Re: K102013
Trade/Device Name: Digital Retinal Camera, Model CR-2
Regulation Number: 21 CFR 886.1120
Regulation Name: Opthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: October 21, 2010
Received: October 22, 2010

Dear Mr. Kubo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K102013

OCT 2 9 2010

Device Name: CR-2

Indications for Use:

The device is intended to be used for taking digital images of the retina of the human eye without a mydriatic.

Prescription Use X (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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